REMARKS

This application is a broadening reissue application that is being filed within two years of the issue date of U.S. Patent No. 6,264,659. Claims 1-24 are now pending. Claims 1 and 12-22 have been amended. Original claims 2-11 remain unchanged. Claims 23-24 have been added. The new claims do not recapture subject matter surrendered during prosecution of U.S. Patent No. 6,264,659.

Reissue Oath/Declaration

The reasoning for this broadening reissue is set forth in the unexecuted Reissue Application Declaration by the Inventor, submitted herewith, wherein the patentees assert that they claimed less than they had the right to claim in the patent.

Conclusion

Applicants' earnestly believe that all of the claims are in condition for allowance, and action towards that end is respectfully requested.

If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney at the number indicated.

Respectfully submitted,

Date: July 24, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Application No.: Not Assigned	)	Atty. Docket No.: 044RE1
Filed: December 8, 1999	)	Examiner: Not Assigned
Patent No.: 6,264,659	)	Art Unit: Not Assigned
Granted: July 24, 2001	)	
Patentees: Anthony C. Ross Peter A. Guagliano	)	
For: Method of Treating an Intervertebral Disk	)	

STATEMENT OF STATUS/SUPPORT FOR CHANGES TO CLAIMS (37 C.F.R. § 1.173(c))

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Box Reissue

Dear Sir:

Applicants respectfully request that this Statement of Status/Support for claim changes be entered prior to examination of the above-identified application.

Claim Status

Claims 1-24 are now pending. Claims 1 and 12-22 have been amended. Original claims 2-11 remain unchanged. Claims 23-24 have been added. The status of the pending claims is as follows.

CLAIM	STATUS
1	Currently Amended
2-11	Original
12-21	Currently Amended
23-24	New

Explanations For Amendments To Claims

The support in the disclosure of U.S. Patent No. 6,264,659 for the changes made to the claims (*i.e.,* amended claims 1 and 12-22 and new claims 23-24) is found in at least the following sections of the '659 patent set forth below under the respective claim(s).

Claim 1 has been amended as follows:

Claim 1 (currently amended): A process of replacing nucleus pulposus of an intervertebral disk, comprising:

~~identifying a location of a rupture in an annulus fibrosus of an intervertebral disk;~~

removing nucleus pulposus associated with [[said]] an annulus fibrosus of [[said]] an intervertebral disk; and

injecting a thermoplastic material heated to a temperature over 50 C. for flowing into said annulus fibrosus and then permitting said material to cool for setting in a non-flowing state upon reaching a temperature of between 35 C. and 42 C., so as to cause said material to occupy a space formerly occupied by said nucleus pulposus.

Line No.	Support For Amendment
4	Figure 3 (nucleus pulposus removed from areas adjacent to the rupture, aperture or hole 14, as well as the interior away from said rupture, aperture or hole 14) Column 1, lines 30-32 (annulus fibrosus may be accessed by via tear or puncture) Column 1, lines 32-35 (annulus fibrosus may be accessed by ruptured or prolapsed) Column 1, lines 43-45 (disk site may be surgically accessed)

Claim 12 has been amended as follows:

Claim 12 (currently amended): [[The]] An injection device ~~as defined in claim 4~~ for injecting thermoplastic material, the injection device comprising:

a heating element and a needle for dispensing of the thermoplastic material. ~~wherein the thermoplastic material comprises a geometric isomer of natural rubber.~~

Line No.	Support For Amendment
1-3	Figure 3 (injection device 22 with needle 38 and heater 28 dispensing thermoplastic material 20) Column 2, line 12-15 (injection of a thermoplastic material heated to a predetermined temperature for injection into the nucleus pulposus in a flow state) Column 2, lines 61-67 (an injection device utilized for heating and injecting the thermoplastic material, the device may utilize a silver needle encased in ceramics) Column 4, line 53-56 (A heater 28 is provided to heat the thermoplastic material)

Claim 13 has been amended as follows:

Claim 13 (currently amended): The injection device as defined in claim [[4]] 12, wherein said ~~heater~~ heating element heats said thermoplastic material for flowing at a temperature between about 150C and 200C.

Line No.	Support For Amendment
1-2	Figure 3 (showing a heating element 28 provided to heat the thermoplastic material) Column 4, line 53-56 (a heater 28 is provided to heat the thermoplastic material)
2-3	Column 5, lines 21-27 (Generally the lowest temperature to which the thermoplastic material is heated while utilizing a large diameter needle such as 1 centimeter in diameter with a relatively high axial force may be 50 C. while the highest temperature will be less than about 250 C. The optimum temperature is about 185 C. within an optimum range between about 150 C. and 200 C.)

Claim 14 has been amended as follows:

Claim 14 (currently amended): The injection device as defined in claim [[4]] 12, wherein said thermoplastic material comprises a linear crystalline polymer.

Line No.	Support For Amendment
1-2	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta percha is a linear crystalline polymer which melts at a predetermined temperature a random but distinct change in structure results.)

Claim 15 has been amended as follows:

Claim 15 (currently amended): The injection device as defined in claim [[4]] 12, wherein said thermoplastic material comprises a gutta percha compound in which gutta percha is between 15% and 40% by weight of the compound.

Line No.	Support For Amendment
1-3	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta percha is a linear crystalline polymer which melts at a predetermined temperature a random but distinct change in structure results.) Column 2, lines 45-52 (A suitable gutta percha compound is dental gutta percha which contains by weight only about 20% gutta percha with zinc oxide comprising about 60% to 75% of the material. The remaining 5% to 10% consists of various resins, waxes, and metal sulfates. The percentages listed are directed to an optimum gutta percha compound. The preferred percentage of gutta percha is in the range of 15% to 40%.)

Claim 16 has been amended as follows:

Claim 16 (currently amended): The injection device as defined in claim [[4]] 12, wherein said injection needle is formed of a ceramic material.

Line No.	Support For Amendment
1-2	Figure 3 (An injection needle 38 preferably formed of silver extends from body 24 and has a ceramic sheath 40 about a portion of needle 38.) Column 2, lines 63-66 (The injection device may utilize a silver needle, encased in ceramics, of about 20 to 30 centimeters in length with a diameter as high as 1 centimeter.)

Claim 17 has been amended as follows:

Claim 17 (currently amended): The injection device as defined in claim [[4]] 12, further comprising:

an expandable sleeve about said needle adjacent an extending end of said needle to define an annulus between said needle and said sleeve, so that pressurized fluid communicating with the annulus expands said sleeve outwardly.

Line No.	Support For Amendment
1-3	Figure 7 (A detachable balloon dilator sleeve 106 extends about the extending end of needle 104 having lateral openings 107.)
4-5	Figure 7 (Piston 108 is effective to pressurize the fluid for flow through openings 107 for expansion of sleeve 106 as shown in broken lines in FIG. 7. Dilator sleeve 106 upon injection of needle 104 in a disk of the spine is expanded for exerting an expanding force against the disk.)

Claim 18 has been amended as follows:

Claim 18 (currently amended): The injection device as defined in claim 17, wherein said needle has openings thereon for the supply of a pressurized fluid to said annulus for expanding said sleeve.

Line No.	Support For Amendment
1-3	Figure 7 (A detachable balloon dilator sleeve 106 extends about the extending end of needle 104 having lateral openings 107. Piston 108 is effective to pressurize the fluid for flow through openings 107 for expansion of sleeve 106 as shown in broken lines in FIG. 7.)

Claim 19 has been amended as follows:

Claim 19 (currently amended): The injection device as defined in claim [[4]] 12, further comprising:

a chamber for receiving a plug of said thermoplastic material;

a piston adjacent an end of said plug for exerting a force against said plug; and

a hand operated trigger is operatively connected to said piston and upon actuation is effective to force said thermoplastic material from said needle when said thermoplastic material is heated to a flowing state.

Line No.	Support For Amendment
1-3	Figure 3 (Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20.) Figure 6 (A generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material.) Column 4, lines 51-53 (Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20.) Column 6, lines 13-15 (A generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material.)
4	Figure 7 (a piston for pressurizing the fluid) Column 6, lines 56-59 (Also shown in FIG. 7 as an attachment is a disk dilator assembly generally indicated at 100 having a cylindrical chamber 102 with an inert fluid such as saline therein and a piston 108 for pressurizing the fluid.)
5-7	Figure 3 (a hand operated trigger for activating a force) Column 4, lines 59-62 (A hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needle 38 upon heating of the thermoplastic material 20 to a predetermined temperature.)

Claim 20 has been amended as follows:

Claim 20 (currently amended): The injection device as defined in claim [[4]] 12, further comprising;

a chamber for receiving a plug of said thermoplastic material; and

a hand operated trigger operatively connected to said plug thermoplastic material and upon actuation is effective to force said thermoplastic material from said needle when said thermoplastic material is heated to a flowing state.

Line No.	Support For Amendment
1-3	Figure 3 (Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20.) Figure 6 (A generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material.) Column 4, lines 51-53 (Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20.) Column 6, lines 13-15 (A generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material.)
4-6	Figure 3 (a hand operated trigger for activating a force) Column 4, lines 59-62 (A hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needle 38 upon heating of the thermoplastic material 20 to a predetermined temperature.)

Claim 21 has been amended as follows:

Claim 21 (currently amended): The injection device as defined in claim [[4]] 20, ~~further comprising;~~ wherein:

[[the]] said chamber for receiving [[the]] said plug is provided in a plunger removable from an injection device body.

Line No.	Support For Amendment
4	Figure 3 (Referring particularly to FIG. 3, injection of thermoplastic material 20 within the annulus fibrosus 12 by an injection device or gun illustrated schematically at 22 is shown. Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20.) Column 2, line 66 - Column 3, line 4 (The size of the needle may depend on such factors as the amount of thermoplastic material to be injected, the temperature of the thermoplastic being injected, and the axial pressure applied by the injection device, such as a piston or plunger, to the thermoplastic material to force the heated material from the end of the needle into the spine.) Column 4 lines 48-50 (Referring particularly to FIG. 3, injection of thermoplastic material 20 within the annulus fibrosus 12 by an injection device or gun illustrated schematically at 22 is shown. Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20.)

Claim 22 has been amended as follows:

Claim 22 (currently amended): The injection device [[asa]] as defined in claim [[4]] 12, further comprising;

a heater control unit having an adjustable temperature control to provide a selected temperature for said ~~heater~~ heating element.

Line No.	Support For Amendment
1	Column 2, lines 61-67 (an injection device utilized for heating and injecting the thermoplastic material, the device may utilize a silver needle encased in ceramics)
3-4	Figure 3 (A heater 28 is provided to heat the thermoplastic material 20 and a heater control unit 30 having an adjustable temperature control knob 32 is provided with a temperature readout at 34.) Column 4, lines 53-56 (A heater 28 is provided to heat the thermoplastic material 20 and a heater control unit 30 having an adjustable temperature control knob 32 is provided with a temperature readout at 34.)

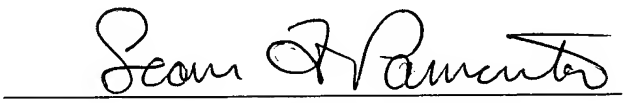
New claims 23-24 find support as follows:

Claim No.	Support For Addition
23	Column 2, lines 28-29 (Gutta percha is a linear crystalline polymer which melts at a predetermined temperature a random but distinct change in structure results)
24	Column 2, lines 12-17 (The present invention is particularly directed to a process for treating the spine including the injection of a thermoplastic material heated to a predetermined temperature for injection into the nucleus pulposus in a flowing state where it cools and sets at body temperature into a non-flowing state.) Column 2, lines 61-63 (An injection device, such as an injection gun, is utilized for heating and injecting the thermoplastic material under a predetermined pressure within the spine.) Column 4, lines 48 – Column 5, lines 27 (Description of use of device to heat thermoplastic material and inject into annulus fibrosus to cool to form a resilient cushion)

If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney at the number indicated.

Respectfully submitted,

Date: July 24, 2003



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